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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,932	07/29/2002	Frank Luyten	522-1783	1230

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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,932	Applicant(s) LUYTEN ET AL.	
	Examiner Louise N. Leary	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-50 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-3-2002</u> . | 6) <input type="checkbox"/> Other: ____. |

1. Claims 29-50 are pending in this application.

2. Claims 29-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(I) Claim 29 is indefinite because the phrase "in vivo assay" is inconsistent with step "-d evaluating the formed cartilage histologically for stable non-vascularised cartilage in vivo." It is noted that tissue cells "histologically" is an in vitro assay.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are:

(a) a step for selecting cells identified with desired positive molecular markers, and (b) a step for purifying the cells selected for further evaluation and use.

(II) In all occurrences in the claims, the phrase "in an amount equivalent to" does not recite "at least 1×10^6 chondrocytes" and therefore renders the claims indefinite because the meaning of the phrase "in an amount equivalent to" can not be determined.

(III) Claim 30 is indefinite because the phrase "using freshly isolated or serially passage cells using..." is unclear. Alternatively, it is unclear if all isolated cells identified with a

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positive or a negative molecular marker are being used in the methods. In addition, it is unclear if "using freshly isolated or serially passage cells using..." contains a typographical error and should read "using freshly isolated or serially passage cells in..."

Claim 30 is also indefinite because the metes and bound intended for the phrase "methods including" can not be determined. It is suggested the "methods including" be changed to ---methods selected from--- to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(IV) In all occurrences in the claims, the phrase "and/or markers co-detectable with these markers and/or reporter..." is indefinite because the metes and bounds intended can not be determined.

(V) Claim 33 is indefinite because it is unclear if the phrase "hybridizing to messenger RNA from cells" means only the cells identified with a positive molecular marker were isolated and selected for hybridization.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are:

(a) a step for selecting cells identified with specific desired positive molecular markers,

(b) a step for purifying the cells selected for further evaluation and use and
(c) a correlation step between "identifying cells with chondrocyte phenotypic stability" and "hybridizing to messenger RNA from cells, sets of DNA probes provided on DNA or DNA chips."

Claim 33 is also indefinite because the claim limitations omit a reference to --- probes---

(VI) Claim 39 and claim 40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are:

- (a) isolating desired cells using specific markers,
- (b) selecting desired cells using specific markers,
- (c) purifying desired cells having a specific marker.

(VII) Claim 41 is indefinite because the claim limitations recite multiple preambles. Alternatively, the claim is indefinite because each preamble recited requires a different set of descriptive claim limitations with a distinct correlation method step to distinctly claim the subject regarded as the invention.

It is suggested that the claims be rewritten as separate claims with one preamble to particularly point out and distinctly claim the subject matter regarded as the invention.

Claim 41 is also indefinite because "an in vivo assay" does not include:

"-to optimize cell culture conditions.." nor "a pharmaceutical composition".

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(VIII) Claim 43 and claim 44 are indefinite because the limitations are not present in a complete sentence.

It is suggested that the language in the claims 43 and 44, line 1 of each, be changed to recite ---A method of transplanting--- to comply with US Patent Practice.

Claims 43 and 44 recites the limitation "selected according to" in lines 3-4 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 43 and 44 recites the limitation "seeding with cells" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim.

(IX) Claim 47 is indefinite because there is no detecting method step(s) nor detection mechanism in claim 33 that describes how to "identify cells with chondrocyte phenotypic stability" using a specific marker.

Also, claim 47 is indefinite because the claim does not recite a correlation step between identifying desired cells and "hybridizing to messenger RNA from cells, sets of DNA probes provided on DNA arrays or DNA chips." Alternatively, the claims do not recite how to specifically prepare the instant DNA chips.

(X) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection

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desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 49 recites the broad recitation "which is greater than 1", and the claim also recites "preferably greater than 2" which is the narrower statement of the range/limitation.

Correction is required to particularly point and distinctly claim the subject matter regarded as the invention.

3. Claims 29-50 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

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4. The Grotendorst reference (US 5,837,258); WO 01/24833, and Schumacher et al reference (J. Orthopaedic Research, V. 17(1), pp. 110-120, (1999) (Abstract Only) have been cited to further show the state of this art.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571)272-0966. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louise N. Leary
Primary Examiner
Art Unit 1654
September 23, 2004